



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/518,322

07/08/2005

Alon Shalev

SC&C-115US

6740

23122 7590 06/27/2008
RATNERPRESTIA
P O BOX 980
VALLEY FORGE, PA 19482-0980

EXAMINER

MALAMUD, DEBORAH LESLIE

ART UNIT

PAPER NUMBER

3766

MAIL DATE

DELIVERY MODE

06/27/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/518,322	Applicant(s) SHALEV, ALON	
	Examiner DEBORAH MALAMUD	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,6,10-14,19,20,23,24,27,30,31,33,34,40,47,48 and 178-184 is/are pending in the application.
- 4a) Of the above claim(s) 1,5,6,10-14,19,20,23,24,27,30,31,33,34 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47,48 and 178-184 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/27/06, 3/2/06, 3/5/07, 7/17/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Claims 1, 5-6, 10-14, 19-20, 23-24, 27, 30-31, 33-34 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04 June 2008.
2. Claims 2-4, 7-9, 15-18, 21-22, 25-26, 28-29, 32, 35-39, 41-46, 49-50, 51-5-83, 84-88 and 89-177 are cancelled; new claims 178-184 are added; claims 1, 5-6, 10-14, 19-20, 23-24, 27, 30-31, 33-34, 40, 47-48 and 178-184 are pending.

Information Disclosure Statement

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3766

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 178-184 are rejected under 35 U.S.C. 102(b) as being anticipated by Shantha et al (U.S. 5,792,100). Shantha discloses (col. 4, lines 1-6) a system and method for treating, among other disorders, Alzheimer's disease. This is accomplished via a device (col. 2, lines 46-49) for stimulating the surface of the sphenoid sinus. This device is a balloon, such that (col. 3, lines 15-18) electrical stimulators are placed along the outer surface, for stimulating the pituitary gland and nerve structures surrounding the sphenoid sinus, which includes (col. 4, lines 50-52) the sphenopalatine ganglion (SPG). Shantha further discloses (col. 7, lines 2-7) "The ability to precisely control this device and provide the precise amount and type of stimulation within a wide range makes its application ideal for treating a number of maladies. Because the stimulation is directed at a specific area, it does not have side effects that affect other parts of the body as in the case of systemic drugs." The Examiner considers this to be applying a signal to SPG related tissue of a subject (including the SPG and nerve fibers which are directly anatomically connected to the SPG); and treating AD by configuring the electrical signal to stimulate the SPG-related tissue. It is noted that since the SPG is a parasympathetic nerve, by admission of the Applicant's own Specification (page 13, lines 28-30), activation of the SPG such as taught by Shantha, would naturally induce parasympathetic activation of the SPG-related tissue (the SPG).

6. Regarding claims 182-183, Shantha discloses (col. 8, lines 13-27 and 45-50) the use of a miniature battery receiver and controller, so that the person can be

ambulatory and engage in normal activities during treatment. The Examiner considers this to be applying intermittent long-term stimulation to the SPG.

7. Regarding claim 184, Shantha discloses (col. 1, lines 13-27) implantation of the device into the nasal cavity, and applying electrical stimulation to the patient.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shantha et al (U.S. 5,792,100) in view of Suzuki et al ("Effect on cortical blood flow of electrical stimulation of trigeminal cerebrovascular nerve fibres on the rat," as disclosed in the Applicant's IDS dated 27 January 2006). Shantha discloses the claimed invention except for configuring the electrical signal so as to cause an increase in cerebral blood flow of the subject. Suzuki however discloses (pages 312-313, "Discussion") stimulation of the NCN (nasociliary nerve, associated with the SPG, in such a way as to increase the cerebral blood flow of rats. It is well-known that blood carries the oxygen and nutrients needed for proper brain function; therefore an increase of blood flow to the brain would necessarily have a salubrious effect on a patient suffering from Alzheimer's disease. Therefore Suzuki and Shantha are in the same field of endeavor. It would have been obvious to one of ordinary skill in the art at the time the invention was made

to modify Shantha's stimulation of the sphenoid sinus, via the SPG, for treatment of AD, with Suzuki's method of stimulating the SPG-associated NCN, in order to increase the blood flow as an adjunct treatment for Alzheimer's disease.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEBORAH MALAMUD whose telephone number is (571)272-2106. The examiner can normally be reached on Monday-Friday, 9.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on (571) 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carl H. Layno/
Supervisory Patent Examiner, Art Unit 3766

/Deborah L. Malamud/
Examiner, Art Unit 3766